UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	))	MDL No. 2804
	)	Case No. 17-md-2804
	)	
This document applies to All Cases	)	Judge Dan Aaron Polster
	)	

SECOND ORDER AMENDING PROTECTIVE ORDER
RE DEA ARCOS/DADS DATABASE

By Order of this Court filed March 6, 2018, at Docket #167, the Court entered an initial Protective Order re the DEA ARCOS/DADS Database.[1] On May 8, 2018, at Docket #400, the Court entered an Amendment to Protective Order to make such Order expressly applicable to Suspicious Order Reports (SORs) produced by DOJ and/or DEA. These two Orders are collectively referred to as the "ARCOS Protective Order." With the agreement of the Department of Justice ("DOJ"), Drug Enforcement Administration ("DEA") except insofar as the motion would permit sharing of ARCOS information with hospitals, which DOJ/DEA opposes because it is outside the scope of routine law enforcement sharing of such information, and the Co-Lead Counsel for the Plaintiffs in MDL No. 2804 ("MDL Counsel"), the Court hereby amends the ARCOS Protective Order in the following respects:

1)   The Court concludes that disclosure of the materials identified in paragraph 2 may be made to counsel for State Attorneys General, cities, counties, Native American Tribes, and hospitals for use in litigation in any court throughout the United States involving the marketing, distribution, sale or use of Opioid related drugs and/or for law enforcement purposes ("Opioid Litigation").

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[1] All references to "Docket #" refer to the master docket in *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (DAP) (N.D. Ohio).

2)   (A) The entirety of the SORs previously produced in this litigation by the DEA; (B) the

entirety of the unprocessed ARCOS data previously produced in this litigation by the DEA; (C)

county level SLCG[2] Processed ARCOS data; and/or (D) county[3] level reports[4]as identified

below:

    1. County Level Distributor Reports that include the following information:

        i. State level summary distributor market share[5] by MME;

        ii. State level summary distributor market share by dosage units;

        iii. State level summary distributor market share by dosage units by distribution center;

        iv. State versus county level market share comparison by total dosage units;

        v. County level summary distributor market share by MME;

        vi. County level summary distributor market share by dosage units;

        vii. County level distributor summary chart;

        viii. County level summary distributor market share by dosage units by distribution center;

        ix. County level per capita total dosage units;

        x. Chart of county level market share and total dosage units per capita;

        xi. County level market share by distributor;

        xii. Charts of county level market share by distributor.

    2. County Level Labeler Reports that include the following information:

        i. County level labeler[6] market share by MME total for 2006 through 2014;

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[2] Securities Litigation and Consulting Group, Inc
[3] As used herein the term county includes parishes.
[4] The county level reports include data for all drugs for which the DEA provided ARCOS data except the two treatment drugs, specifically, methadone and buprenorphine.
[5] Distributor market shares aggregate the market shares attributable to distribution centers owned by the same distributor.
[6] Labeler information was derived using the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration code for each drug and cross referencing against the Food

    ii. County level labeler market share by dosage units total for 2006 through 2014;

    iii. County level labeler market share by MME by year;

    iv. County level labeler market share by dosage units by year;

    v. County level labeler market share data by MME;

    vi. County level market share data by dosage units.

3. County Level Pharmacy Reports that include the following information:

    i. County level summary of opioid shipments of twelve opioid drugs to retail and chain pharmacies[7] within the county by total dosage units, weight in mgs and total MME;

    ii. For the top 100 pharmacies in the county ranked by MME, pharmacy reports, which provide:

        a. opioid shipments by distributor band distribution center by year;

        b. average purchased opioid MME of pharmacies in the county and in the state as well as the percentile rank of this pharmacy's receipts of opioids compared to all pharmacies in the state;

        c. chart of total dosage units by drug family shipped to pharmacy;

        d. chart of total MME by drug family shipped to pharmacy;

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and Drug Administration, National Drug Code Directory and list of NDC/NHRIC Labeler Codes. A list of NDC/NHRIC Labeler Codes is available at: www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm191017.htm. Food and Drug Administration, National Drug Code Directory available at: www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt;   www.deadiversion.usdoj.gov/arcos/ndc/readme.txt. Additionally, the ARCOS Registrant Handbook provides the following definitions relating to labeler: A packer/repacker is a registrant that packs a product into a container (i.e., packer) or repacks a product into different size containers, such as changing a package of 50 capsules to 5 packages of 10 capsules each. A labeler/relabeler is a registrant that affixes the original label to a product (i.e., labeler) or changes in any way the labeling on a product without affecting the product or its container (i.e, relabeler). The "relabel" term implies that the package size remains unchanged with changes being made only in brand name, NDC number, distributor, etc. Registrant Handbook at 6-2, available at: www.deadiversion.usdoj.gov/arcos/handbook/full.pdf#search=arcos%20handbook. Labeler market shares aggregate the market shares attributable to FDA labeler names which reflect slight variations in a parent company name.

[7] Included pharmacies are those identified as Retail Pharmacy or Chain Pharmacy in ARCOS field BUYER_BUS_ACT.

3) County level SLCG Processed ARCOS data and county level reports, as enumerated in C

and D above, will be provided to counsel as follows:

    a. State Attorneys General – county level SLCG Processed ARCOS data and county level reports for all counties in the state;

    b. Cities - county level SLCG Processed ARCOS data and county level reports for the county in which the city is located;

    c. Counties - county level SLCG Processed ARCOS data and county level reports for that county;

    d. Native American Tribes - county level SLCG Processed ARCOS data and county level reports for all counties included, in whole or in part, within its territorial boundaries;

    e. Hospitals - county level SLCG Processed ARCOS data and county level reports for the county in which the hospital is physically located.

4) The MDL Counsel are hereby authorized to transfer the data identified herein and

subsequently provide access to counsel as outlined above.

5) The entirety of the data described in Paragraphs 2 and 3 will be transferred via a secured

website.   Such secured site shall be set up pursuant to Attachment A to this Order.

6) All counsel requesting data outlined in Paragraphs 2 and 3 must read the ARCOS

Protective Order, as amended by this Order, and sign the Acknowledgement of Protective

Order and Agreement to be bound, which is attached as Attachment B to this Order.

7) All other provisions of the ARCOS Protective Order shall remain in full force and effect

as if repeated verbatim herein.

IT IS SO ORDERED.

                                            _____

                                            Dan Aaron Polster
                                            United States District Judge

ATTACHMENT A

Transfer Process and Procedure Transfer Process and Procedure

The MDL shall store the data made available to counsel in Opioid Litigation pursuant to the ARCOS Protective Order on a highly secure online website hosted on Amazon Web Services, "AWS", secured servers. Access to the website and then ability to un-encrypt the data is secured by two separate passwords. The website home page shall have an initial User ID and password dialog box.

    a. When valid User ID and password is entered, the registered user will need to agree to terms and conditions including recognition of the protective order and agreement to security of the data before the registered user can download any data on each visit.

    b. Once the "I Accept" or similar button is struck, Securities Litigation and Consulting Group, Inc. (SLCG) will be notified that the registered user has signed on and has access to a data file.

    c. The registered user will once more accept the terms and conditions before any file download will begin.

    d. The registered user will need a second password, different from the password used to login to the website to unencrypt the downloaded file.

The integrity of the data will be protected by SLCG and by the authorized users who have committed to the protective order as a pre-condition to downloading any data.

ATTACHMENT B

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	))	**MDL No. 2804**
	)	**Case No. 17-MD-2804**
THIS DOCUMENT RELATES TO:	)	
ALL CASES	)	**Judge Dan Aaron Polster**
	)	
	)	**ACKNOWLEDGEMENT OF**
	)	**PROTECTIVE ORDER AND**
	)	**AGREEMENT TO BE BOUND**

The undersigned hereby acknowledges that he/she has read the Protective Order entered in the above-captioned litigation, understands its terms, and agrees to be bound by its terms. The undersigned submits to the jurisdiction of the United States District Court for the Northern District of Ohio in matters relating to the Protective Order. The undersigned understands that the terms of the Protective Order obligate him/her to use documents designated as "CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER" solely for purposes of the action identified in the Affidavit of Counsel or for law enforcement purposes, and that disclosure of any such documents to third-persons is prohibited except in accordance with the Protective Order or with permission of the Court.

Signature

Name (Please Print or Type)

Date